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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,738	02/28/2002	Kevin S. Weadock	15314 (ETH-1636)	8872

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,738

Applicant(s)

WEADOCK ET AL.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 3, 10-12, 16-28, 32, and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9, 13-15, 29-31, 33, and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02/28/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/28/02, 06/11/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: IDS 05/20/04.

DETAILED ACTION***Election/Restrictions***

1. Applicant's election without traverse of Species 1, drawn to claims 1, 2, 4-15, 29-33 and 38-41 in the reply filed on May 12, 2004 is acknowledged.
2. Claims withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on May 15, 2004.
3. However, Claims 10-12 and 32 are also withdrawn as being directed to non-elected species. Claims 10-12 are drawn to an alignment means, which consists of a "plurality of pins protruding..." This claim is clearly in reference to Species II, as represented by Figures 3A-4. Pins 120 are shown in Fig. 3B.

Additionally, Claim 32 is drawn to a hole formed after attaching the second vessel to the body, which describes only Species III, as represented by Figures 5A-5C. This procedure is described in the specification, with reference to Figures 5A-5C on page 16 in the second paragraph.

4. Consequently, claims 1, 2, 4-9, 13-15, 29-31, 33, and 38-41 have been examined.

Claim Objections

5. Claim 4 is objected to because of the following informalities: in line 2 of the claim, Applicant recites "on between". It seems that Applicant would

want to choose either one word or the other, because in the current state the sentence does not make sense. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35

U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 4, 5, 6, 9, 29-31, 33, 38, 39, and 41 are rejected under 35

U.S.C. 102(e) as being anticipated by Publication No. US 2001/0001827 A1 to Chapman. Regarding Claim 1, Chapman discloses a device for creating an end to side anastomosis, as shown in Figure 9. The device comprises a body (30), which is fabricated from a sponge material. In the specification on page 9, Applicant defines a sponge as “any flexible elastomer, polymer or natural material having a porous and/or cellular structure as well as a non-porous and non-cellular structure.” Chapman’s “foam” which is “radially compressible” and has “100 pores per inch” {paragraph [0036]} certainly meets the definition of sponge as given by the Applicant in the specification. Chapman discloses securing the first vessel (10) in the opening of the body (30) with glue {paragraph [0039] last sentence}. Chapman discloses a second securing

means, which secures the end of the first vessel (10) to the hole in the second vessel (12) {paragraph [0042] “one or more sutures can be applied to the anastomosis site to prevent the graft vessel 10 from being pulled out from the target vessel”}.

7. Regarding Claims 4 and 38, the first securing means is glue, and the glue must be placed on the outside of the first vessel (10) and the inside corresponding surface of the opening (30) because that is the only place where the two surfaces contact each other {paragraph [0039] last sentence}.
8. Regarding Claims 5 and 39, Chapman discloses a sealing means (20). The junction of the two vessels (10 and 20) is sealed—i.e. there is no blood leakage {paragraph [001] “for sealingly joining a graft vessel...to the side wall of a target vessel”}.
9. Regarding Claim 6, the catheter and balloon are not structural aspects of the invention, but merely means for helping to seal the vessels. Chapman’s sealing juncture is capable of being effected by such means.
10. Regarding Claim 9, Chapman’s sponge material contains pores and the liquid adhesive (i.e., glue) will certainly flow into those pores {paragraph [0039] last sentence}.
11. Regarding Claim 29, Chapman discloses a method of creating an anastomosis between two vessels, including attaching the first vessel (10) to a sponge-like body (30), attaching a portion of the second vessel (12) to the body (30) and doing it all through an opening in the body (the only way to get inside the body is to go through an opening of some sort).

12. Regarding Claim 30, the distal end of vessel 19 is attached (connected and not becoming separated) to body (30), which is attached to the side of the vessel (12) [Fig. 9]. They are all attached to each other, and the assembly remains as so after the surgery is completed.
13. Regarding Claim 31, Chapman discloses forming a hole in target vessel (12) such as the one in Figure 9.
14. Regarding Claim 33, Chapman's hole (16) is formed before attaching the second blood vessel to the body {paragraph [0041] first sentence}.
15. Regarding Claim 41, Chapman aligns the vessel (10) with the opening in the body (30) so that they can be inserted together—this is evident from Figure 9.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

16. Claims 1, 2, 4, 5, 7, 8, 9, 14, 15, 29-31, 33, 38, 39, and 41, are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,117,147 to Simpson et al. Regarding Claims 1, 2, 4, 5, 7, 29-31, 33, 38, 39, and 41, Simpson discloses a device for creating an end-to-side anastomosis [Column 1, lines 6-9], including a body (18) fabricated from a sponge material. The material is a polymer and is impregnated with a liquid drug [Column 3, lines 17-24], and therefore meets Applicant's definition (and the common definition) of a sponge. Sponge (18) is secured on two different sides using glue, and therefore has two securing/sealing [Column 3, lines 27-30] means. With reference to Figure 5B, sponge (18) is attached to the target vessel at

locations (36) (with glue) [Column 4, lines 18-23; Column 3, lines 27-35] and is attached to member (16) also with glue [Column 4, lines 15-17].

17. Regarding Claim 8, Simpson discloses attaching a graft vessel “to a side wall of a target vessel at an opening in the side wall” [Column 1, lines 6-8] with glue. Therefore, the glue will be at and around the opening of the side wall of the target vessel.
18. Regarding Claim 9, the adhesive is applied to the surface of disk-shaped sponge (18) and will necessarily fill in the interstices of the polymer.
19. Regarding Claims 14 and 15, Simpson discloses impregnating the polymer with an anastomosis modulating agent [Column 3, lines 18-23].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,117,147 to Simpson et al. in view of Publication No. US 2001/0044631 A1 to Akin et al. Simpson’s sponge material is not resorbable, but Akin teaches that the advantage of having a sutureless anastomotic fitting be resorbable is that when it disintegrates, a healed/completely physiologic anastomosis is left behind having no foreign body to contend with the human body’s natural functioning {paragraph [0128]}. Therefore, it would have

been obvious to one having ordinary skill in the art at the time of the invention to form Simpson's sutureless anastomosis disc out of a resorbable material in order to allow the vessel junction to heal normally and to be free from any foreign bodies or substances, as taught by Akin.

21. Claims 6 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. Publication No. US 2001/0001827 A1 to Chapman in view of Publication No. 2002/0065545 A1 to Leonhardt et al. Chapman discloses all of the claimed features of the invention, but fails to disclose using a balloon catheter to urge the outer surface of graft vessel (10) against body (30), sandwiching adhesive between them. However, Leonhardt discloses a graft vessel (24) and a body (10, aorta) and discloses inserting and expanding a balloon inside of graft vessel (24) in order to urge the outer surface of the graft vessel (24) against body (10) to sandwich the adhesion (glue, 56) therebetween {paragraphs [0027, 0028, 0030, 0060, 0083]; Figures 1, 9d, 10a}. Leonhardt teaches that one should use a balloon catheter in order to secure the outside surface of graft vessel ("spring means" 26 specifically and member 24 generally) to the interior surface of body (10) {paragraph [0030], last sentence}. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ a balloon catheter to better secure vessel (10) to body (30), sandwiching adhesive therebetween, as taught by Leonhardt, because a balloon catheter expands the inner member

towards the outer member and will cause them to touch and be secured to each other by glue.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,180,392 to Skeie et al.

U.S. Patent No. 5,634,936 to Linden et al.

U.S. Patent No. 4,503,568 to Madras

Publication No. US 2001/0001827 to Chapman

Publication No. US 2003/0153932 to Spence et al.

Publication No. US 2003/0065346 to Evens et al.

Publication No. US 2004/0073238 to Makower

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP
August 12, 2004

A handwritten signature in black ink, reading "Julian W. Woo".

JULIAN W. WOO
PRIMARY EXAMINER